

Summary of Safety and Effectiveness

Submitted by:	Dan Reigle Regulatory Affairs Merit Medical Systems, Inc. 1600 West Merit Parkway South Jordan, UT 84095-2416 (801) 253-1600 (801) 253-1684 fax	MERIT MEDICAL SYSTEMS, INC. 1600 WEST MERIT PARKWAY SOUTH JORDAN, UTAH 84095 801-253-1600 FAX 801-253-1651
Contact Person:	Same as above	
Date Summary Prepared:	September 13, 2000	
Device Name:	InQwire™ Diagnostic Guide Wire	
Common Name:	Guide Wire	
Trade Name:	InQwire™	
Classification:	Class II Wire, Guide, Catheter 21 CFR 870.1330 Product Code DQX	
Predicate Device	K863178 UMI Steerable Guide Wire	

Product Description

The InQwire guide wire is manufactured in a clean room environment using stainless steel with an external lubricious coating. It is packaged in a plastic hoop which is fitted with a luer hub.

Intended Use

Merit Medical guide wires are used to facilitate the placement of devices during diagnostic and interventional procedures.

Substantial Equivalence:

Substantial equivalence was judged on the following facts:

- + Merit is the manufacturer of the predicate device
- + The modified device is manufactured from the same materials
- + The modified device has the same intended use
- + The modified device has the same shelf life
- + The modified device is packaged with the same materials
- + The modified device complies with the requirements of ISO 11070 Standard entitled "Sterile single-use intravascular catheters introducers" which includes specific requirements for diagnostic guide wires.

Tests performed:

The following tests were performed to validate the modified device:

Test	Result
Tensile strength	Passed
Torque strength	Not required
Torqueability	Not required
Tip flexibility	Passed
Coating adherence/Integrity	Passed
Biocompatibility	Not required
Catheter compatibility	Passed
Corrosion resistance	Passed

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT - 4 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Chester McCoy
Regulatory Affairs Engineer
Merit Medical Systems, Inc.
1600 West Merit Parkway
South Jordan, UT 84095-2416

Re: K002289
Trade Name: InQwire™ Diagnostic Guide Wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: September 13, 2000
Received: September 19, 2000

Dear Mr. McCoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

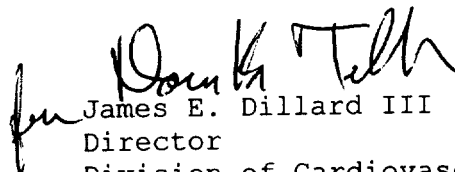
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

James E. Dillard III
Director

Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

510(k)
Number
(if Known)


K 002289

Device Name InQwire™ Diagnostic Guide Wire

Indications for Merit Medical guide wires are to facilitate the placement of devices during diagnostic and interventional procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K002289

Prescription Use X

OR

Over-The-Counter Use _____